



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of: Maurine Pearson and
Teresa Leigh Barr**

Group Art Unit: 1654

Serial No.: 10/614,925

Examiner: Not Assigned

Filed: July 08, 2003

**For: Emu-Based Compositions for Mental
Well-Being and Method of Use**

Atty Dkt No.: 1067.08

CERTIFICATE OF FIRST CLASS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope, addressed to MAIL STOP DD, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the following date: February 11, 2004.

Wendy B. Buskop
Wendy K. B. Buskop

MAIL STOP DD
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

- I. Applicants hereby submit an Information Disclosure Statement and enclose a Form PTO-1449 listing references A1-A9 and B1-B3 for consideration by the Examiner. Copies of each listed reference are not enclosed. However enclosed are references B1-B3.
- II. Applicants hereby request the Examiner to consider each cited reference. As required under 37 C.F.R. § 1.98(a)(3)(i), the following are concise explanations of the relevance of each reference, as they are presently understood:

REFERENCE A1: "A dosage form is disclosed for administering 10 ng to 1200 mg tacrine to a patient in need of tacrine therapy.."

REFERENCE A2: "The present invention is directed to the discovery that topical or parenteral administration of emu oil to a mammal stimulates the proliferation of skin. Emu oil can be used to treat skin wrinkles and rejuvenate aged and photo-damaged skin. It has also been discovered that emu oil can be topically applied to stimulate melanogenesis in the skin and to stimulate hair growth. Thus, emu oil is useful to treat pigmentation disorders such as hypopigmentation, stimulating melanogenesis to enhance skin tanning, and treating disorders relating to disturbances in hair cycling such as alopecia, male pattern baldness, female baldness, and chemotherapy-induced alopecia."

REFERENCE A3: "Emu oil is therapeutically used in methods for lowering cholesterol, triglycerides and low density lipoproteins and increasing high density lipoproteins; preventing and treating allergies; preventing scarring; treating headaches; preventing nose bleeds; treating and preventing cold and flu symptoms; and relieving discomfort associated with menstruation. Additionally, emu oil acts as an effective chemical buffer in combination with glycolic acid."

REFERENCE A4: "Disclosed is a method for transporting neurologic therapeutic agents to the brain by means of the olfactory neural pathway and a pharmaceutical composition useful in the treatment of brain disorders.."

REFERENCE A5: "This invention discloses a method for treating a patient for an illness selected from the group consisting of amnesia, head injuries, Alzheimer's disease, epileptic dementia, presenile dementia, post traumatic dementia, senile dementia, vascular dementia and post stroke dementia or individuals otherwise seeking memory enhancement. The method comprises providing a compound of formula (1) (1) wherein (a) R1 and R2 are the same or different and are selected from the group consisting of hydrogen and a lower alkyl group of 1 to 6 carbon atoms and (b) the ring system ABCD is asteroid nucleus selected from the group consisting of estrone, dehydroepiandrosterone, estradiol, estradiolester, pregnenolone, substituted estrone, substituted dehydroepiandrosterone, substituted estradiol, substituted estradiolesters and substituted pregnenolone. The invention also discloses the enhancement of memory by the steroid sulfatase inhibitors of the invention acting synergistically with the naturally occurring neurosteroids dehydroepiandrosterone sulfate (DHEAS) and pregnenolone sulfate (PS)."

REFERENCE A6: "Emu oil is therapeutically used in methods for lowering cholesterol, triglycerides and low density lipoproteins and increasing high density lipoproteins; preventing and treating allergies; preventing scarring; treating

headaches; preventing nose bleeds; treating and preventing cold and flu symptoms; and relieving discomfort associated with menstruation. Additionally, emu oil acts as an effective chemical buffer in combination with glycolic acid."

REFERENCE A7: "The use is described of acetyl D-carnitine and its pharmacologically acceptable salts in the therapeutic treatment of glaucoma. The medicament may be administered orally or parenterally or be applied as a collyrium containing approximately 1-10% w/v of acetyl D-carnitine."

REFERENCE A8: "A biologically active component of emu oil is disclosed which is useful in pharmaceutical composition for the treatment of inflammation of environmental and systemic origins. Pharmaceutical composition including emu oil and dermal transport enhancing compounds are also disclosed as useful topical anti-inflammatory treatments."

REFERENCE A9: "This invention relates to the treatment of presenile or senile dementia and in particular to the treatment of Alzheimer's disease. It is proposed that such conditions may be combatted or their effects alleviated by the administration of a physiologically acceptable lithium compound and/or of an essential fatty acid or a physiologically acceptable salt thereof and there are described herein methods of treatment of such conditions."

REFERENCE B1: "PURPOSE: To obtain a medicine containing docosahexaenoic acid as an active ingredient, capable of improving the depression of volition due to the dementia, delirium, the aggravation of interpersonal relation, dromomania, the deficiency of composure, and the lowering of calculation ability, judgment ability and higher functions, etc., and having no side effect.
CONSTITUTION: This improving medicine contains docosahexaenoic acid, and its salt, ester, glyceride, phospholipid, choline compound, ascorbic acid compound, and an amino acid compound usually in an amount of 10-100wt.% (preferably 50-100wt.%). An oil containing the docosahexaenoic acid includes a fish oil extracted from a blue back fish such as sardine, mackerel, horse mackerel, salmon or saucy pike, a fish oil originated from the orbital fatty oil of a large sea fish such as tuna or bonito, a fatty oil originated from a microorganism, a krill oil, a sea product-originated fatty oil extracted from the livers of cod or cuttlefish. The dementia symptom-improving medicine is usually administered at a dose of 100-2000mg per day in one to several proportions a day."

REFERENCE B2: "PURPOSE: To provide a treating agent containing vitamin B6, a chalybeate and coenzyme Q10 as active ingredients, having an excellent activity for improving verbal memory and performance memory, generally

active to dementias such as Alzheimer's dementia and cerebrovascular dementia and not having side- effects.

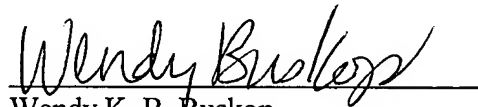
CONSTITUTION: The treating agent contains vitamin B6, a chalybeate and coenzyme Q10 as active ingredients. The coenzyme Q10 is a known compound generally used as a medicine and is known as an ubidecarenone preparation. The vitamin B6 is used as a drug and known as a pyridoxal phosphate preparation. The chalybeate includes ferrous sodium citrate preparation (ferromia) employed for asiderotic anemia. This treating agent, the coenzyme Q10, the vitamin B6 and the chalybeate may be separately administered, but the substantial administration required is the combined use of these three ingredients."

REFERENCE B3: "This invention provides a method for transdermal transporation of proteins, peptides and other therapeutic agents using oil obtained from the sebaceous glands of rhea and emu birds. The method may also be used to facilitate transport across other animal membranes."

III. No fees are believed to be due in connection with these materials. This Information Disclosure Statement is being filed prior to receipt of an official Office Action.

Respectfully submitted,

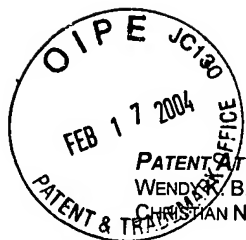
Date: February 11, 2004



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February 11, 2004

File No. 1067.08

CERTIFICATE OF FIRST CLASS MAIL

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Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

RE: *U.S. Patent Application Serial No. 10/614,925;*
Entitled: "Emu-Based Compositions for Mental Well-Being and Method of Use;"
Inventors: Maurine Pearson and Teresa Leigh Barr.

Sirs:

Enclosed for filing in the above-mentioned application is:

- (1) An Information Disclosure Statement;
- (2) A Form PTO-1449 listing references A1-A9 and B1-B3;
- (3) Copies of references B1-B3; and
- (4) A postcard. Please date stamp and return the enclosed postcard to evidence receipt of these materials.


BUSKOP LAW GROUP, P.C.

Serial Application No. 10/614,925
February 11, 2004

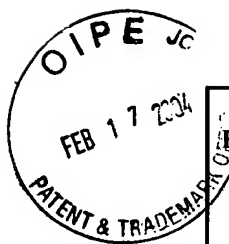
Attorney Docket No. 1067.08
Page 2 of 2

No fees are believed to be due in connection with these materials. However, the Commissioner is hereby authorized to charge any deficiencies to Deposit Account No 50-1313 in the name of Buskop Law Group. A duplicate copy of this transmittal is enclosed.

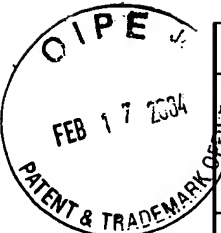
Respectfully submitted,



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Reg. No. 32,202



Form PTO 1449	U.S. Department of Commerce Patent and Trademark Office	Serial No.: 10/614,925	Group Art Unit: 1654					
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Filing Date: July 08, 2003						
		Applicant(s): Maurine Pearson and Teresa Leigh Barr						
		Atty. Docket No.: 1067.08						
A REFERENCE - U.S. PATENT DOCUMENTS								
Document Number	Examiner Initial*	Patent Number	Date	Name	Class	Sub Class	Filing Date If Appropriate	
A1		6,036,973	03/14/00	Guittard	424	457	07/15/97	
A2		5,958,384	09/28/99	Holick	424	60	04/27/98	
A3		5,662,921	09/02/97	Fein	424	436	06/07/95	
A4		5,624,898	04/29/97	Frey, II	514	12	12/22/94	
A5		5,556,847	09/17/96	Johnson	514	178	11/27/94	
A6		5,472,713	12/05/95	Fein	424	522	11/23/94	
A7		5,432,199	07/11/95	Cavazza	514	546	04/23/91	
A8		5,431,924	07/11/95	Ghosh	424	522	11/14/90	
A9		4,753,964	06/28/88	Horrobin	514	558	01/27/87	
B REFERENCE - FOREIGN PATENT DOCUMENTS								
Document Number	Examiner Initial*	Patent Number	Date Of Filing	Country	Class	Sub Class	Translation	
							Yes	No
B1		JP 08231391		JAPAN	A61K	31/20		X
B2		JP 04049235		JAPAN	A61K	31/20		X
B3		WO 98/33474	01/30/97	PCT	A61K	7/40	X	



C REFERENCE - OTHER DOCUMENTS (Including Author, Title, Date, Pages, Etc.)		
Document Number	Examiner Initial*	Other Documents Citation
C1		
Examiner:		Date Considered:
*Examiner:	Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	